

SUNSCREEN SPF30- non nano zinc oxide cream
SUNSCREEN FOR FACE SPF30- non nano zinc oxide cream
AFTERSUN- non nano zinc oxide cream
DIAPER RASH CREAM- non nano zinc oxide cream
SUNSCREEN FOR KIDS SPF50- non nano zinc oxide cream
S.O.S REPAIR CREAM- non nano zinc oxide cream
SBS BILIMSEL BIO COZUMLER SANAYI VE TICARET ANONIM Sirketi

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Package Label - Principal Display Panel



Natural mineral sunscreen formulated with non-nano zinc oxide to protect you and your loved ones from the harmful effects of sun.

Drug Facts

*Helps protect the skin against the harmful effects of the sun.
Made with natural ingredients. Suitable for sensitive skin.*

Active Ingredients

Purpose

Non-nano Zinc Oxide 15% Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply liberally 15 minutes before sun exposure.
■ Children under 6 months of age: Ask a doctor. **Reapply:** ■ After 80 minutes of swimming or sweating ■ Immediately after towel drying
■ At least every 2 hours.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Aqua, Caprylic / Capric Triglyceride, Coco - Caprylate / Caprate, Aloe Barbadensis Leaf Juice, Polyglyceryl-2 Dipolyhydroxystearate, Silica, Butyrospermum Parkii (Shea) Butter, Simmondsia Chinensis (Jojoba) Seed Oil, Dicaprylyl Carbonate, Glyceryl Citrate / Lactate / Linoleate / Oleate, Polyglyceryl-3 Diisostearate, Polyglyceryl-4 Diisostearate / Polyhydroxystearate / Sebacate, Panthenol, Magnesium Sulfate, Cera Alba, Polyhydroxystearic Acid, Polyglyceryl-3 Oleate, Propolis Extract, Diisostearyl Polyglyceryl-3 Dimer Dilinoleate, Tocopheryl Acetate, Xylityl Sesquicaprylate, Xanthan Gum, Parfum.

Sunscreen SPF3080 mL

NDC: 82123-001



Natural mineral sunscreen formulated with non-nano zinc oxide to protect your kids and the whole family from the harmful effects of the sun.

Drug Facts

*Helps protect the skin against the harmful effects of the sun.
Made with natural ingredients. Suitable for sensitive skin.*

Active Ingredients

Purpose

Non-nano Zinc Oxide 22%..... Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply liberally 15 minutes before sun exposure.

■ Children under 6 months of age: Ask a doctor. **Reapply:** ■ After 80 minutes of swimming or sweating ■ Immediately after towel drying

■ At least every 2 hours.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Aqua, Coco-Caprylate / Caprate, Dicaprylyl Carbonate, Olus Oil, Butyrospermum Parkii Butter, Silica, Polyglyceryl-2 Dipolyhydroxystearate, Panthenol, Aloe Barbadensis Leaf Juice, Glyceryl Citrate / Lactate / Linoleate / Oleate, Polyglyceryl-3 Diisostearate, Cetearyl Alcohol, Magnesium Sulfate, Propolis Extract, Tocopheryl Acetate, Xylityl Sesquicaprylate, Parfum.

Sunscreen for kids

SPF5080 mL NDC: 82123-002





Natural mineral sunscreen to protect your face from the harmful effects of the sun. Specifically formulated to hydrate and moisturize your face.

Drug Facts

Helps protect the skin against the harmful effects of the sun.

Made with natural ingredients. Suitable for sensitive skin.

Active Ingredients

Purpose

Non-nano Zinc Oxide 15%..... Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under 6 months of age: Ask a doctor. **Reapply:** ■ After 80 minutes of swimming or

sweating ■ Immediately after towel drying
■ At least every 2 hours.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Inactive Ingredients: Aqua, Coco-Caprylate / Caprate, Caprylic / Capric Triglyceride, Olea Europaea Oil, Aloe Barbadensis Leaf Juice, Polyglyceryl-3 Diisostearate, Polyglyceryl-2 Dipolyhydroxystearate, Silica, Dicaprylyl Carbonate, Panthenol, Glycerin, Magnesium Sulfate, Butyrospermum Parkii (Shea) Butter, Glyceryl Citrate/ Lactate / Linoleate / Oleate, Polyhydroxystearic Acid, Propolis Extract, Tocopheryl Acetate, Cera Alba, Polyglyceryl-4 Diisostearate / Polyhydroxystearate / Sebacate, Xylityl Sesquicaprylate, Polyglyceryl-3 Oleate, Diisostearyl Polyglyceryl-3 Dimer Dilinoleate, Parfum.

Sunscreen for face SPF3040 mL

NDC: 82123-003





Natural after sun lotion to soothe your skin and moisturize it after sun exposure.

Drug Facts

Helps protect the skin against the harmful effects of the sun.
Made with natural ingredients. Suitable for sensitive skin.

Active Ingredients

Purpose

Non-nano Zinc Oxide 2% Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply generously to all areas of the skin for soothing relief. ■ Gently massage into affected areas ■ Reapply as frequently as you like ■ For best results, apply right after sun burn occurs.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Aqua, Butyrospermum Parkii Butter, Coco-Caprylate / Caprate, Sesamum Indicum Seed Oil, Glycerin, Panthenol, Aloe Barbadosensis Leaf Juice, Cetearyl Alcohol, Glyceryl Citrate / Lactate / Linoleate/ Oleate, Hydrogenated Lecithin, Silica, Cera Alba, Pentylene Glycol, Xylityl Sesquicaprylate, Propolis Extract, Sodium Stearoyl Glutamate, Physalis Angulata Extract, Tocopheryl Acetate, Caprylic / Capric Triglyceride, Xanthan Gum, Parfum.

AfterSun80 mL NDC: 82123-004





Natural baby diaper cream for babies to prevent and heal rashes and soothe the skin

Drug Facts

Active Ingredients

Non-nano Zinc Oxide 22%-----

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps seal out wetness

Warning;

For external use only.

When using this product • do not get into eyes

Stop use and ask a doctor if • condition worsen • symptoms last more than 7 days or clear up and occur within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Change wet or soiled diapers promptly
- Cleanse the diaper area and allow to dry
- Apply cream liberally as often as necessary with each diaper change especially at bedtime or any time exposure to wet diapers.

Other Information

- Store between 20° to 25°C (68° to 77°F)
- Do not use if safety seal is broken

Inactive Ingredients

Butyrospermum Parkii Butter, Olus Oil, Simmondsia Chinensis Seed Oil, Panthenol, Coco-Caprylate / Caprate, Aloe Barbadensis Leaf Juice, Glycerin, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Jojoba Esters, Helianthus Annuus Seed Wax, Aqua, Propolis Extract, Diisostearyl Polyglyceryl-3 Dimer / Diisoleate, Acacia Decurrens Flower Wax, Cera Alba, Polyglyceryl-4 Diisostearate / Polyhydroxystearate / Sebacate, Caprylic / Capric Triglyceride, Polyglyceryl-3 Oleate, Tocopheryl Acetate, Polyglycerin-3

Diaper Rash Cream 50 mL NDC:

82123-005



Drug Facts	
Active Ingredient	Purpose
Non-nano Zinc Oxide 4%	skin protectant
Uses	
■dries the oozing and weeping of poison: ■ivy ■oak ■sumac ■helps prevent and temporarily protects chapped or cracked lips ■prevent and protect from the drying effects of wind and cold weather	
Warnings	
For external use only. ■When using this product: ■do not get into eyes ■Stop use and ask a doctor if ■condition worsens ■symptoms last more than 7 days or clear up and occur again within a few days	
Directions Apply as needed	
Other Information Store at room temperature	
Inactive Ingredients Olea Europaea Oil, Cera Alba, Aqua, Soybean Glycerides, Butyrospermum Parkii (Shea) Butter Unsaponifiables, Glycerin, Honey, Propolis Extract, Royal Jelly, Tocopheryl Acetate, Panthenol, Parfum*	

*Produced naturally from essential oils.

SOS Repair Cream

SUNSCREEN SPF30			
non nano zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	12 mg in 80 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)			
JOJOBA OIL (UNII: 724GKU717M)			
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)			
WHITE WAX (UNII: 7G1J5DA97F)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
POLYGLYCERYL-3 OLEATE (UNII: XRQ165498B)			
PROPOLIS WAX (UNII: 6Y8XYV2NOF)			

DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE (UNII: G3232Z5S2O)	
PANTHENOL (UNII: WW9CM0O67Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82123-001-81	1 in 1 TUBE	06/28/2021	
1	NDC:82123-001-80	80 mL in 1 TUBE; Type 0: Not a Combination Product		



BEE & YOU.
SKINCARE

NATURAL MINERAL SUNSCREEN



NON
NANO

30⁺
SPF

NON
GMO

UVA UVB

PROPOLIS
MINERAL ZINC OXIDE
SHEA BUTTER
ALOE VERA

80 ML

Magnesium Sulfate, Cera Alba, Polyhydroxystearic Acid, Polyglyceryl-3 Oleate, Propolis Extract, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Tocopheryl Acetate, Xylityl Sesquicaprylate, Xanthan Gum, Parfum.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2021	

SUNSCREEN FOR FACE SPF30

non nano zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 mg in 40 mL

Inactive Ingredients

Ingredient Name	Strength
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PANTHENOL (UNII: WW9CM0O67Z)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
GLYCERYL CITRATE (UNII: 4987GT719I)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WHITE WAX (UNII: 7G1J5DA97F)	
POLYGLYCERYL-3 OLEATE (UNII: XHQ165498B)	
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE (UNII: G323Z25S2O)	
ARGAN OIL (UNII: 4V59G5UW9X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82123-003-41	1 in 1 TUBE	06/28/2021	
1	NDC:82123-003-40	40 mL in 1 TUBE; Type 0: Not a Combination Product		



BEE & YOU.
SKINCARE

NATURAL MINERAL SUNSCREEN
for FACE

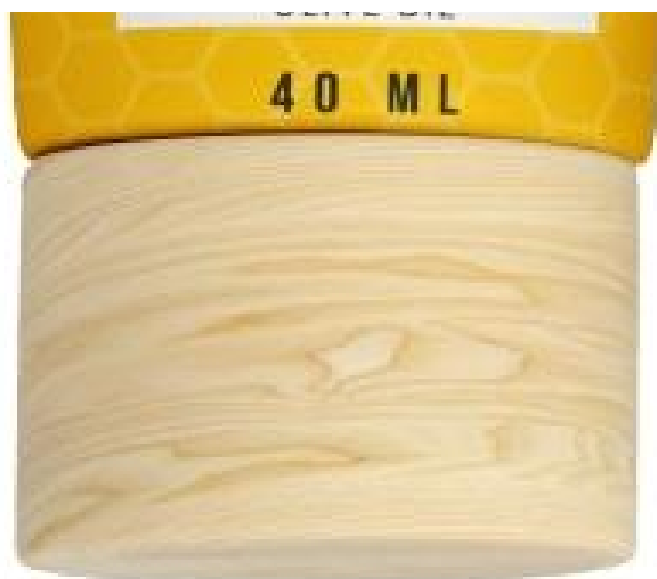


30⁺
SPF



UVA UVB

PROPOLIS
MINERAL ZINC OXIDE
OLIVE OIL



Natural mineral sunscreen to protect your face from the harmful effects of the sun. Specifically formulated to hydrate and moisturize your face.

Drug Facts

Helps protect the skin against the harmful effects of the sun.

Made with natural ingredients. Suitable for sensitive skin.

Active Ingredients

Purpose

Non-nano Zinc Oxide 15%_____ Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply liberally 15 minutes before sun exposure. ■ Children under 6 months of age: Ask a doctor. **Reapply:** ■ After 80 minutes of swimming or sweating ■ Immediately after towel drying ■ At least every 2 hours.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Inactive Ingredients: Aqua, Coco-Caprylate / Caprate, Caprylic / Capric Triglyceride, Olea Europaea Oil, Aloe Barbadensis Leaf Juice, Polyglyceryl-3 Diisostearate, Polyglyceryl-2 Dipolyhydroxystearate, Silica, Dicaprylyl Carbonate, Panthenol, Glycerin, Magnesium Sulfate, Butyrospermum Parkii (Shea) Butter, Glyceryl Citrate/ Lactate / Linoleate / Oleate, Polyhydroxystearic Acid, Propolis Extract, Tocopheryl Acetate, Cera Alba, Polyglyceryl-4 Diisostearate / Polyhydroxystearate / Sebacate, Xylityl Sesquicaprylate, Polyglyceryl-3 Oleate, Diisostearyl Polyglyceryl-3 Dimer Dilinoleate, Parfum.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2021	

AFTERSUN

non nano zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.6 mg in 80 mL

Inactive Ingredients

Ingredient Name	Strength
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL CITRATE (UNII: 4987GT719I)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
WHITE WAX (UNII: 7G1J5DA97F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WW9CM0O67Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
SESAME OIL (UNII: QX10HYY4QV)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ARGAN OIL (UNII: 4V59G5UW9X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82123-004-81	1 in 1 TUBE	06/28/2021	
1	NDC:82123-004-80	80 mL in 1 TUBE; Type 0: Not a Combination Product		



BEE & YOU.
SKINCARE

NATURAL AFTER SUN LOTION



MOISTURIZES

**COOLING
EFFECT**



NON
OILY



Natural after sun lotion to soothe your skin and moisturize it after sun exposure.

Drug Facts

*Helps protect the skin against the harmful effects of the sun.
Made with natural ingredients. Suitable for sensitive skin.*

Active Ingredients

Non-nano Zinc Oxide 2%

Purpose

Sunscreen

Use: Apply liberally to the skin 15-30 minutes before going outdoors. Reapply every 2 hours, or more often if sweating or towel-drying.

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning: For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply generously to all areas of the skin for soothing relief. ■ Gently massage into affected areas ■ Reapply as frequently as you like ■ For best results, apply right after sun burn occurs.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Aqua, Butyrospermum Parkii Butter, Coco-Caprylate / Caprate, Sesamum Indicum Seed Oil, Glycerin, Panthenol, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Glyceryl Citrate / Lactate / Linoleate/ Oleate, Hydrogenated Lecithin, Silica, Cera Alba, Pentylene Glycol, Xylityl Sesquicaprylate, Propolis Extract, Sodium Stearoyl Glutamate, Physalis Angulata Extract, Tocopheryl Acetate, Caprylic / Capric Triglyceride, Xanthan Gum, Parfum.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2021	

DIAPER RASH CREAM

non nano zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11 mg in 50 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)	
WHITE WAX (UNII: 7G1J5DA97F)	
POLYGLYCERYL-3 OLEATE (UNII: XRQ165498B)	
PANTHENOL (UNII: WW9CM0O67Z)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
JOJOBA OIL (UNII: 724GKU717M)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
PALM OIL (UNII: 5QUO05548Z)	
PALM KERNEL OIL (UNII: B0S90M0233)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CANOLA OIL (UNII: 331KBj17RK)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82123-005-51	1 in 1 TUBE	06/28/2021	
1	NDC:82123-005-50	50 mg in 1 TUBE; Type 0: Not a Combination Product		



BEE & YOU.
BABY **CARE**

NATURAL DIAPER RASH CREAM



PROPOLIS
MINERAL ZINC OXIDE
PANTHENOL
SHEA BUTTER

50 ML



Natural baby diaper cream for babies to prevent and heal rashes and soothe the skin

Drug Facts

Active Ingredients

Non-nano Zinc Oxide 22%-----

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps seal out wetness

Warning;

For external use only.

When using this product • do not get into eyes

Stop use and ask a doctor if • condition worsen • symptoms last more than 7 days or clear up and occur within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Change wet or soiled diapers promptly
- Cleanse the diaper area and allow to dry
- Apply cream liberally as often as necessary with each diaper change especially at bedtime or any time exposure to wet diapers.

Other Information

- Store between 20° to 25°C (68° to 77°F)

- Do not use if safety seal is broken

Inactive Ingredients

Butyrospermum Parkii Butter, Olus Oil, Simmondsia Chinensis Seed Oil, Panthenol, Coco-Caprylate / Caprate, Aloe Barbadensis Leaf Juice, Glycerin, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Jojoba Esters, Helianthus Annuus Seed Wax, Aqua, Propolis Extract, Diisostearyl Polyglyceryl-3 Dimer / Dinoleate, Acacia Decurrens Flower Wax, Cera Alba, Polyglyceryl-4 Diisostearate / Polyhydroxystearate / Sebacate, Caprylic / Capric Triglyceride, Polyglyceryl-3 Oleate, Tocopheryl Acetate, Polyglycerin-3

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2021	

SUNSCREEN FOR KIDS SPF50

non nano zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.6 mg in 80 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
PALM KERNEL OIL (UNII: B0S90M0233)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CANOLA OIL (UNII: 331KBJ17RK)	
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
ARGAN OIL (UNII: 4V59G5UW9X)	

GLYCERYL CITRATE (UNII: 4987GT719I)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WW9CM0O67Z)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PALM OIL (UNII: 5QUO05548Z)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82123-002-81	1 in 1 TUBE	06/28/2021	
1	NDC:82123-002-80	80 mg in 1 TUBE; Type 0: Not a Combination Product		



BEE & YOU.
SKINCARE

NATURAL MINERAL SUNSCREEN

KIDS



50⁺
SPF

UVA UVB



PROPOLIS
MINERAL ZINC OXIDE
SHEA BUTTER
ALOE VERA

80 ML

Natural mineral sunscreen formulated with non-nano zinc oxide to protect your kids and the whole family from the harmful effects of the sun.

Drug Facts

*Helps protect the skin against the harmful effects of the sun.
Made with natural ingredients. Suitable for sensitive skin.*

Active Ingredients

Purpose

Non-nano Zinc Oxide 22%..... Sunscreen

Uses: ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning; For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Directions: ■ Apply liberally 15 minutes before sun exposure.

■ Children under 6 months of age: Ask a doctor. **Reapply:** ■ After 80 minutes of swimming or sweating ■ Immediately after towel drying

■ At least every 2 hours.

Other Information Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Aqua, Coco-Caprylate / Caprate, Dicaprylyl Carbonate, Olus Oil, Butyrospermum Parkii Butter, Silica, Polyglyceryl-2 Dipolyhydroxystearate, Panthenol, Aloe Barbadensis Leaf Juice, Glyceryl Citrate / Lactate / Linoleate / Oleate, Polyglyceryl-3 Diisostearate, Cetearyl Alcohol, Magnesium Sulfate, Propolis Extract, Tocopheryl Acetate, Xylityl Sesquicaprylate, Parfum.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2021	

S.O.S REPAIR CREAM

non nano zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82123-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.6 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
WHITE WAX (UNII: 7G1J5DA97F)	
PANTHENOL (UNII: WW9CM0O67Z)	
HONEY (UNII: Y9H1V576FH)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ARGAN OIL (UNII: 4V59G5UW9X)	
ROYAL JELLY (UNII: L497I37F0C)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 82123			

1	NDC:82123-006-16	1 in 1 BOX	11/11/2021	
1	NDC:82123-006-15	15 mL in 1 CONTAINER; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/11/2021	

Labeler - SBS BILIMSEL BIO COZUMLER SANAYI VE TICARET ANONIM SIRKETI (519951069)

Registrant - SBS BILIMSEL BIO COZUMLER SANAYI VE TICARET ANONIM SIRKETI (519951069)

Establishment

Name	Address	ID/FEI	Business Operations
SBS BILIMSEL BIO COZUMLER SANAYI VE TICARET ANONIM SIRKETI		519951069	manufacture(82123-001, 82123-002, 82123-003, 82123-004, 82123-005, 82123-006)

Revised: 11/2021

SBS BILIMSEL BIO COZUMLER SANAYI VE TICARET ANONIM SIRKETI